



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Patel et al.

Serial No.: 10/613,698

Attorney Docket No.: 03-40102-US

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Examiner: Ghali, Isis A D

Art Unit: 1615

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REPLY BRIEF

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This reply brief is filed in response to the Examiner's Answer mailed October 17, 2007,
and by the deadline of December 17, 2007.

The Commissioner is hereby authorized to charge any fees which may be required during
the entire pendency of the appeal, or credit any overpayment, to Deposit Account 18-0586.

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I. Real Party in Interest:

The real party in interest in is as stated in Applicant's Opening Brief.

II. Related Appeals and Interferences:

Applicant's statement on the related appeals and interferences is incorporated by reference from Applicant's Opening Brief.

III. Status of Claims:

Claims 1-18, 34, and 35 are pending. Claims 19 and 21-33 were withdrawn and claim 20 was cancelled. Claims 1, 2, 5-18, 34, and 35 were finally rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement, in an Office Action mailed October 25, 2006. This rejection has been withdrawn pursuant to the Examiner's Answer mailed October 17, 2007. *See* Examiner Answer, p. 3. Except for the foregoing, the status of the claims is as stated in Applicant's Opening Brief.

IV. Status of Amendments:

No amendments have been filed subsequent to the Final Rejection.

V. Summary of Claimed Subject Matter:

The Summary of the Invention is as stated in Applicant's Opening Brief.

VI. Grounds of Rejection to be Reviewed:

Except for Issue 1, which has been withdrawn by the Examiner, the Grounds of Rejection to be Reviewed is as stated in Applicant's Opening Brief.

VII. Grouping of Claims:

The grouping of claims is as stated in the Applicant's Opening Brief.

VIII. Argument:

Applicant reasserts each of the arguments set forth in the Opening Brief as they apply to each of the issues discussed herein.

The Examiner has not addressed numerous of Applicant's arguments raised in Applicant's Opening Brief as required by MPEP § 1208 ("The answer should contain a response to the allegations or arguments in the brief[.]") Further, the Examiner makes numerous repeated legal and factual errors as set forth herein. Therefore, in this section, we will address the errors most often repeated by the Examiner first and then analyze each issue separately.

The Examiner Confuses the Viscosity of a Composition with the Viscosity of its Separate Components and Incorrectly Applies Inherent Anticipation.

Throughout prosecution and in the Examiner's answer, the Examiner has admitted that the prior art of record does not disclose the claimed viscosity of the composition and has asserted that viscosity is inherent, relying on *Atlas Powder Co. v. Ireco Inc.* to support her assertion. See Final Office Action, p. 6-7 and 10 and Examiner Answer, p. 4 and 15-16. However, the Examiner misunderstands the law of inherency as explained in *Atlas*. The claimed viscosity is not inherent in the cited art.

As discussed in Applicant's opening brief, viscosity is determined by a number of factors, only one of which is the identity of ingredients. Applicant has explained that there are other important determinants of viscosity, such as the *quantity* of each ingredient. See Opening Brief, p. 21-23. Applicant has also set forth a detailed explanation of viscosity and has provided examples of how viscosity varies based on the different factors. See Opening Brief, p. 21-22.

Further, Applicant has shown how the present invention has overcome the problems in the prior art with the claimed viscosity of the composition. *See* Opening Brief, p. 24-25.

Applicant would like to point out the burden the Examiner has with respect to inherency arguments. The Examiner must provide rationale or evidence tending to show the inherency she asserts. MPEP §2112; *see also Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (“In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art”) (emphasis in original)). “The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.” MPEP §2112, IV (emphasis in original).

In *Atlas*, the patent claimed an old composition. *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999). The prior art reference in *Atlas* explicitly disclosed all of the claim limitations except one – the presence of air in the mixture. *Id.* at 1346. That one limitation was inherently present because “prills” described in the prior art reference had interstitial and porous air that served necessarily to provide air as called for by the claim. *Id.* at 1349. Thus, the missing “air” limitation necessarily flowed from the prills described in the prior art reference. In contrast, the prior art of record here does not explicitly disclose the viscosity limitation, and the viscosity limitation does not necessarily flow from a mere ingredient list. The claimed invention is a novel system where the viscosity of a composition containing at least one insoluble dermatologically active ingredient is controlled to allow the composition to be effectively used with a pad delivery vehicle, which has not been successful in the past.

Functional Language Must Be Considered

The Examiner also asserts that the claims “do not recite any specific viscosities, other than the functional language concerning viscosity.” Examiner Answer, p. 14. The Examiner dismisses the viscosity limitation without considering it and fails to meet her burden of establishing that this element is taught in the prior art because she considers the viscosity limitation as being merely “functional language.” The Examiner’s position is contrary to law. See, e.g. MPEP §2173.05(g). “A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used.” MPEP §2173.05(g). Had the Examiner considered the viscosity limitation as she was required, she would have determined that this element is not taught by any of the prior art of record.

Therefore, since the claimed viscosity is not taught in the prior art of record and the claimed viscosity does not necessarily flow from the prior art as described in *Atlas*, the present invention is not anticipated or rendered obvious by the prior art of record.

The Examiner Ignores Claim Elements, Incorrectly Labeling them as Intended Uses

In numerous instances, the Examiner ignores claim limitations, arbitrarily labeling them as intended use. These limitations (such as “the viscosity is effective to substantially uniformly deliver the composition to the skin when the pad is wiped on the skin”) are not intended uses, but rather further specify the viscosity of the composition. None of the cited references teach or suggest such a viscosity; therefore those references have been incorrectly applied by the Examiner.

Issue 1

Whether claims 1, 2, 5-18, 34, and 35 comply with the written description requirement under 35 U.S.C. §112, first paragraph.

The Examiner has withdrawn this rejection. *See* Examiner Answer, p. 3.

Issue 2

Whether claims 1, 2, 6, 7, and 14-18 are unpatentable under 35 U.S.C. §102(b) over the ‘642 Patent.

Applicant notes that the Examiner has not fully responded to Applicant’s arguments raised in the Opening Brief and the Examiner has not met her burden of establishing that the ‘642 Patent anticipates the claimed invention. The Examiner incorrectly uses the inherency analysis under *Atlas* and misunderstands viscosity as discussed above at pages 10-12.

The Examiner also attempts to show anticipation by merely stating that “since the claims do not recite any specific composition for the emulsion and consequently no amounts then the reference anticipates the claims because [] [the ‘642 Patent] teaches the desired function because it does not teach leakage of the emulsion from the pad to the container and teaches impregnation of the pad with the emulsion composition.” Examiner’s Answer, p. 15. The Examiner tries to show the viscosity limitation by the ‘642 Patent’s silence, which the Examiner improperly manipulates to mean it teaches the present invention. Again, without support for her assertions or providing a declaration as requested on numerous occasions, the Examiner has failed to show the ‘642 Patent teaches the viscosity element or that it necessarily flows from the compositions of the ‘642 Patent.

The '642 Patent does not anticipate claim 1 or claims 2, 6, 7, and 14-18 which depend therefrom. Therefore, this rejection should be removed.

a. Group 2 – Claim 2

In addition to the arguments set forth above, the '642 Patent does not teach a viscosity that is effective to substantially uniformly deliver the composition to skin when the pad is wiped on the skin. This is an example of when the Examiner incorrectly labeled a claim limitation as an intended use. *See* p. 12, *supra*. This rejection should be removed.

Issue 3

Whether claims 1, 2, 6, 7, 14, and 16-18 are unpatentable under 35 U.S.C. §102(b) over the '766 Patent.

Applicant notes that the Examiner has not fully responded to Applicant's arguments raised in the Opening Brief and the Examiner has not met her burden of establishing the '766 Patent anticipates the claimed invention.

The Examiner incorrectly uses the inherency analysis under *Atlas* and misunderstands viscosity as discussed above at pages 10-12. Thus, the '766 Patent fails to anticipate the claimed invention.

Again the Examiner tries to show anticipation by merely stating that,

since the claims do not recite any specific composition for the emulsion and consequently no amounts, then the reference anticipates the claims because it teaches the desired function because it does not teach leakage of the emulsion from the pad to the container and teaches impregnation of the pad with the emulsion composition. US '766 recognized the desire to increase

the viscosity of the composition to allow retention of the composition into the substrate (col. 4, lines 33-37), as applicants have done.

Examiner Answer, p. 17. The Examiner tries to show the viscosity limitation by the ‘766 Patent’s silence, which the Examiner improperly manipulates to mean it teaches the present invention. The Examiner does not know whether the emulsion of the ‘766 Patent leaks and if the emulsion does not leak from the pad, she does not know why. Thus, without support for her assertions or providing a declaration as previously requested by the Applicant, the Examiner has failed to show the ‘766 Patent teaches the viscosity element of the claims.

Further, the Examiner cites “col. 4, lines 33-37” of the ‘766 Patent, which only states, “[o]ptionally, the lipophiilic [sic] skin moisturizing agent can be thickened using a thickening agent. Suitable thickening agents for the lipophiilic [sic] skin moisturizing agent include polacrylates [sic]; fumed silica [sic] natural and synthetic waxes, crystalline hydroxy-containing waxes such a trihydroxystearin, alkyl silicone waxes such as behenyl silocone wax . . .” It is important to point out that the lipophilic skin moisturizing agent is only one component of the moisturizing phase of the composition. Just because the ‘766 Patent says that viscosity of one of the components can be adjusted, does not mean that the ‘766 Patent says that viscosity of the entire liquid should be adjusted at all, much less that it should be adjusted to the claimed range.

Therefore, since the ‘766 Patent fails to teach each and every element of the claims, it cannot anticipate claim 1 or claims 2, 6, 7, 14, and 16-18 that depend therefrom. This rejection should be removed.

a. Group 2 – Claim 2

In addition to the arguments set forth above, the ‘766 Patent does not disclose that the viscosity is effective to substantially uniformly deliver the composition to skin when the pad is wiped on the skin. This is an example of when the Examiner incorrectly labeled a claim limitation as an intended use. *See* p. 12, *supra*.

Therefore, the ‘766 Patent cannot and does not anticipate claim 2. This rejection should be removed.

Issue 4

Whether claims 3-5, 8-13, 34, and 35 are unpatentable under 35 U.S.C. §103(a) over the ‘642 Patent.

The Examiner has not fully responded to Applicant’s arguments and the Examiner has not met her burden of establishing a *prima facie* case of obviousness.

The Examiner incorrectly uses the inherency analysis under *Atlas* and misunderstands viscosity as discussed above at pages 10-12. Thus, the ‘642 Patent fails to render the claimed invention obvious.

The Examiner again argues that “the claimed particle sizes and viscosities do not impart patentability to the claims, absent evidence to the contrary.” Examiner Answer, p. 5. The Examiner’s argument is wrong and fails to examine the claims as a whole as required by MPEP §2143.03. The particle sizes and viscosities are not taught in the prior art and do impart patentability.

The Examiner again asserts that the reference teaches or suggests the desired function because “it does not teach leakage of the emulsion from the pad to the container and teaches impregnation of the pad with the emulsion composition.” Examiner Answer, p. 19-20. The Examiner again tries to show the viscosity limitation by the ‘642 Patent’s silence, which the Examiner improperly manipulates to mean it teaches the present invention. Without support for her assertions or providing a declaration as requested on numerous occasions, the Examiner has failed to show the ‘642 Patent teaches or suggests the viscosity element of the claims.

The Examiner also asserts that,

[a]ppellants define the viscosity of the claimed composition by its function and method of its measuring, and the burden is on applicants to show that the functions of the claimed composition resulted in novel and unobvious difference between the claimed product and prior art product since the Patent Office does not have the facilities for preparing and measuring the claimed viscosities and comparing them with the prior art inventions.

Examiner Answer, p. 20. Applicant has repeatedly explained the novel and unobvious differences between the claimed invention and the prior art of record and yet the Examiner continues to ignore these differences. In particular, Applicant describes the critical nature of the viscosity and the problems overcome in the prior art by the present invention. Opening Brief, p. 8-9; *see also* Specification, p. 2-4.

Therefore, the ‘642 Patent does not render the claims obvious.

Objective Evidence of Non-obviousness

Even assuming *arguendo* that the Examiner had met the burden of establishing a *prima facie* case of obviousness, Applicant has refuted the obviousness rejection. Applicant has overcome the problems in the prior art and has satisfied the long felt need for a pad delivery

system for insoluble dermatologically active ingredients. *See* Opening Brief, p. 31. Further, Applicant's invention produces a new and unexpected result as previously argued. *See* e.g. Response to the Office Action mailed February 8, 2006, p. 15 and Opening Brief, p. 35-36.

Therefore, assuming *arguendo* that a *prima facie* case of obviousness was made, long felt need and unexpected result have been proven overcoming this rejection, which should be removed.

a. Group 3 – Claims 4, 5, 34, and 35

In addition to the arguments set forth above, the '642 Patent also does not teach or suggest the specific active ingredient particle sizes as claimed in claims 4, 5, 34, and 35 (Group 3). The Examiner is only able to respond to the Applicant's arguments by asserting that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the particle sizes, since the art teaches using granules or powders, and implies retention of the granules or particles in the applicator." Examiner Answer, p. 20-21. The Examiner has failed to set forth any support for her assertions. There is no teaching or suggestion of particle sizes in the '642 Patent. The mere discussion of granules and powders is not a teaching or suggestion of specific particle sizes.

The Examiner also asserts that "the particle sizes are result effective variables because changing them will clearly affect the type of product obtained." Examiner Answer, p. 20-21. The law is well-settled that a factor must first be recognized as a "result-effective variable," before it can be obvious to optimize it. *See*, e.g. MPEP §2144.05. *See also In re Antonie*, 559 F.2d 618 (CCPA 1977). The prior art has not recognized the claimed viscosity or the particle sizes as result-effective variables. The '642 Patent's silence regarding the viscosity of the

claimed invention and the particle sizes cannot and does not lend itself to mere optimization and thus, the claimed invention is not obvious over the prior art.

Therefore, the '642 Patent cannot and does not render the claims obvious and the rejection should be removed. Further, even if a *prima facie* case of obviousness was established, long felt need and unexpected result (*See* p. 17-18, *supra*) have been proven and the rejection should be removed.

b. Group 4 – Claims 8, 9, 10, 11, and 12

In addition to the arguments set forth above, the '642 Patent also does not disclose the specific viscosities as described in claims 8-12 (Group 4). The Examiner offers no support for the assertion that this additional limitation is obvious. The Examiner merely dismisses these claims elements by stating that “appellants’ attention is directed to the broadness of the claims that recite no specific ingredients resulting in the claimed viscosity” without support. Examiner Answer, p. 21. In light of the fact that the '642 Patent fails to even mention the viscosity, much less the specific ranges called for by claims 8-12, the '642 Patent cannot and does not render the claims obvious and the rejection should be removed. Further, even if a *prima facie* case of obviousness was established, long felt need and unexpected result (*See* p. 17-18, *supra*) have been proven overcoming the rejection, which should be removed.

Issue 5

Whether claims 3-5, 8-13, 34 and 35 are unpatentable under 35 U.S.C. §103(a) over the '766 Patent.

The Examiner has not fully responded to Applicant's arguments and the Examiner has not met her burden of establishing a *prima facie* case of obviousness. The Examiner incorrectly uses the inherency analysis under *Atlas* and misunderstands viscosity as discussed above at pages 10-12. Thus, the '766 Patent fails to render the claimed invention obvious.

The Examiner again asserts the unfounded argument that the "reference teaches the desired function because it does not teach leakage of the emulsion from the pad to the container and teaches impregnation of the pad with the emulsion composition." Examiner Answer, p. 22. This is incorrect as set forth at pages 14-15. The Examiner tries to show the viscosity limitation by the '766 Patent's silence, which the Examiner improperly manipulates to mean it teaches the present invention. Again, without support for her assertions or providing a declaration as previously requested by the Applicant, the Examiner has failed to show the '766 Patent teaches or suggests the viscosity element of the claims.

The Examiner also asserts that "[a]ppellants define the viscosity of the claimed composition by its function and method of its measuring [sic], and the burden is on applicants to show that the functions of the claimed composition resulted in novel and unobvious difference [sic] between the claimed product and prior art product since the Patent Office does not have the facilities for preparing and measuring the claimed viscosities and comparing them with the prior art inventions." Examiner Answer, p. 22. Applicant has shown throughout prosecution that the functions of the claimed composition resulted in novel and unobvious differences between the

claimed product and prior art product. In particular, Applicant describes the critical nature of the viscosity and the problems overcome in the prior art by the present invention. Opening Brief, p. 21-23.

Since the '766 Patent does not teach or suggest the claim limitations of claim 1, the '766 Patent cannot render claims 3-5, 8-13, 34, and 35 obvious at least by virtue of their ultimate dependence on independent claim 1; but also because their additional limitations, such as specific active ingredient particle sizes and specific viscosities, are not taught or suggested by the '766 Patent.

Therefore, a *prima facie* case of obviousness has not been established, and assuming *arguendo* it was, long felt need and unexpected result (*See* p. 17-18, *supra*) have been proven overcoming this rejection, which should be removed.

a. Group 3 – Claims 4, 5, 34, and 35

In addition to the arguments set forth above, the '766 Patent also does not disclose the specific active ingredient particle sizes as described in claims 4, 5, 34, and 35 (Group 3). The Examiner asserts that “the US '766 recognized that the suitable sizes of the particles to be delivered to the skin from a pad impregnated with an emulsion is between 0.2 and 200 micron” and that one of ordinary skill in the art “would have provided any particles within that range to be certain of its delivery through the skin pore.” Examiner Answer, p. 23. Applicant has previously explained that the teaching of the '766 Patent is with respect to the droplet size of the emulsion, not the size of insoluble particles. *See* Opening Brief, p. 27. None of Applicant's claims pertain to the droplet size of the moisturizing phase of the emulsion. Rather, the claims of the present invention pertain to the particle size of the insoluble dermatologically active

ingredient. The Examiner fails to understand this difference. Thus, the Examiner's argument is unfounded and fails to establish a *prima facie* case of obviousness.

The Examiner again incorrectly asserts her "result-effect variable argument," which is unfounded as discussed above at pages 18-19. Examiner Answer, p. 23. Not only has the Examiner failed to show that the particle sizes are taught or suggested by the '766 Patent, she has also failed to show that the particle sizes are recognized in the prior art as a result-effective variable. Thus, the present invention is not a matter of merely discovering an optimum value.

Therefore, the '766 Patent cannot and does not render the claims obvious and the rejection should be removed. Further, even if *arguendo* a *prima facie* case of obviousness was established, long felt need and unexpected result (*See* p. 17-18, *supra*) have been proven overcoming the rejection, which should be removed.

b. Group 4 – Claims 8, 9, 10, 11, and 12

In addition to the arguments set forth above, the '766 Patent also does not teach the specific viscosities as described in claims 8-12 (Group 4). In response to Applicant's arguments, the Examiner, merely states that "appellants' attention is directed to the broadness of the claims that recite no specific ingredients resulting in the claimed viscosity" and repeats her arguments under her anticipation and obviousness rejections. Examiner Answer, p. 24. In light of the fact that the '766 Patent fails to teach or suggest the viscosity of the claimed invention and the fact that the Examiner refused to consider all of the elements of the claims, the '766 Patent cannot and does not render the claims obvious and the rejection should be removed. Further, even if a *prima facie* case of obviousness was established, long felt need and unexpected result (*See* p. 17-18, *supra*) have been proven overcoming the rejection, which should be removed.

Issue 6

Whether claims 4, 5, 34, and 35 are unpatentable under 35 U.S.C. §103(a) over the ‘642 Patent in view of the ‘766 Patent.

The Examiner has not fully responded to Applicant’s arguments and the Examiner has not met her burden of establishing a *prima facie* case of obviousness.

The Examiner again tries to assert that the ‘766 Patent teaches what she terms as “particle sizes of the emulsion” and therefore teaches the particle sizes of the active ingredient of the claims. As discussed at pages 20-21, this argument is wholly incorrect.

The references are silent as to the viscosity and the active ingredient particle sizes. The ‘642 Patent and the ‘766 Patent fail to even mention the viscosity or active ingredient’s particle sizes, much less the specific ranges called for by claims 4, 5, 34, and 35. Further the Examiner incorrectly asserts her “result-effective variable argument.” *See* p. 18-19, *supra*.

Therefore, since the ‘642 Patent and the ‘766 Patent, even if *arguendo* they could be properly combined, do not teach or suggest each and every claim element, the references do not render the claimed invention obvious and the rejection should be removed. Further, even if a *prima facie* case of obviousness was established, long felt need and unexpected result (*See* p. 17-18, *supra*) have been proven overcoming the rejection, which should be removed.

Issue 7

Whether claim 15 is unpatentable under 35 U.S.C. §103(a) over the ‘766 Patent in view of the ‘642 Patent.

The Examiner has not fully responded to Applicant’s arguments and the Examiner has not met her burden of establishing a *prima facie* case of obviousness.

Claim 15 is dependent on claim 1. As discussed above, the ‘766 Patent and the ‘642 Patent do not teach or suggest all of the claim elements and therefore do not render the claimed invention obvious. Therefore, even if the ‘766 Patent and the ‘642 Patent were properly combined, the Examiner has not met her burden for establishing that claim 15 is obvious in light of the ‘766 Patent and the ‘642 Patent and the rejection should be removed. Further, even if a *prima facie* case of obviousness was established long felt need and unexpected result (*See* p. 17-18, *supra*) have been proven overcoming the rejection.

Issue 8

Whether claims 1-18, 34, and 35 are unpatentable under 35 U.S.C. §103(a) over the ‘145 Patent in view of the ‘642 Patent.

The Examiner has not fully responded to Applicant’s arguments and the Examiner has not met her burden of establishing a *prima facie* case of obviousness. The Examiner incorrectly uses the inherency analysis under *Atlas* and misunderstands viscosity as discussed above at pages 10-12.

The Examiner makes a nonsensical argument that “the present claims recite the viscosity is measured for 60 seconds, while US ‘145 teaches viscosity less than 150 mPa.second, therefore, when the present viscosity measured for one second [sic] will overlap with the viscosity disclosed by U.S. ‘145.” Examiner Answer, p. 26. The Examiner’s conversion not only defies logic, but destroys the viscosity measurement of mPa.second. The Examiner cannot convert a measurement taken over 60 seconds into one second because by doing so (in an incorrect conversion), she has changed the viscosity measurement into a pressure measurement of mPa. Pressure is not viscosity and cannot be used to anticipate or render obvious the viscosity limitation.

The ‘145 Patent is also silent with respect to particle size of the insoluble dermatologically active ingredient. However, the Examiner asserts that “the US ‘145 recognized that the suitable sizes of the particles to be delivered to the skin from a pad impregnated with an emulsion is between 50 and 1000 micron and also teaches that the emulsion droplets are suitable for impregnation in the substrate, [which] implies that the active agents including BPO having particle sizes within this range in order to be impregnated into the substrate.” Examiner’s Answer, p. 27. Further, the Examiner asserts that one of ordinary skill in the art “would have provided any particles within that range to be certain of its impregnation in the substrate and its delivery through the skin pores.” Examiner’s Answer, p. 27. The Examiner’s argument has no support. The only specific discussion of size is with respect to the globules of the fatty phase in an oil-in-water emulsion, which are not the particle size of the dermatologically active ingredient. *See* ‘145 Patent, Col. 7, lines 62-65 and Col. 8, lines 28-32. Further, even if the globule size were relevant, which it is not, the size of “between 50 and 1000 micron” for the globules constituting the fatty phase as asserted by the Examiner is actually measured in

nanometers not microns. *See* ‘145 Patent, Col. 7, lines 62-65. A simple conversion of nanometers to micrometers results in globules sizes of 0.50 to 1 micron, which is substantially below the claimed particle size. Further, while the pore size of the substrate is irrelevant to Applicant’s claimed particle size, the ‘145 Patent only mentions that the “substrate may be of any size and shape that is suitable for the desired aim” and does not specifically set forth any pore size of the substrate. *See* ‘145 Patent, Col. 8, lines 28-32. Thus, the ‘145 Patent fails to teach or suggest the claimed invention.

Again, the Examiner incorrectly asserts her “result-effective argument” regarding particle size. *See* p. 18-19, *supra*. Therefore, since the ‘145 Patent and the ‘642 Patent, even if properly combined, do not teach or suggest each and every claim element, the references do not render the claimed invention obvious and the rejection should be removed. Further, even if a *prima facie* case of obviousness was established, long felt need and unexpected result (*See* p. 17-18, *supra*) have been proven overcoming this rejection, which should be removed.

a. Group 2 – Claim 2

In addition to the arguments set forth above, the ‘145 Patent and the ‘642 Patent also do not teach the limitations of claim 2 (Group 2). Specifically, the ‘145 Patent and the ‘642 Patent fail to teach or suggest a viscosity effective to substantially uniformly deliver the composition to skin when the pad is wiped on the skin. This is an example of when the Examiner incorrectly labeled a claim limitation as an intended use. *See* p. 12, *supra*.

Therefore, not only does the ‘145 Patent in view of the ‘642 Patent fail to teach or suggest the viscosity of claim 2, they also fail to teach or suggest a viscosity such that the composition is substantially uniformly delivered. Thus, even if the ‘145 Patent and the ‘642

Patent were properly combined, they do not render claim 2 obvious because they do not teach or suggest all of the claim limitations. Further, even if a *prima facie* case of obviousness was established, long felt need and unexpected result (*See* p. 17-18, *supra*) have been proven overcoming the rejection, which should be removed.

b. Group 3 – Claims 4, 5, 34, and 35

In addition to the arguments set forth above, the ‘145 Patent also fails to teach or suggest the specific active ingredient particle sizes of claims 4, 5, 34, and 35 (Group 3). *See* p. 24-25, *supra*.

Again, the Examiner incorrectly asserts her “result-effective variable argument” about particle size. *See* p. 18-19, *supra*.

Therefore, even if the ‘145 Patent and the ‘642 Patent were properly combined, they do not render the claimed invention obvious because they do not teach or suggest each and every claim element. Further, even if a *prima facie* case of obviousness was established, it has been rebutted by the Applicant’s showing that the invention meets long felt but unmet needs and unexpected result (*See* p. 17-18, *supra*), which should be removed.

c. Group 4 – Claims 8, 9, 10, 11, and 12

In addition to the arguments set forth above, the ‘145 Patent and the ‘642 Patent also do not teach or suggest the specific viscosities using specific viscometers as described in claims 8-12 (Group 4). In response to Applicant’s arguments, the Examiner, merely states that “appellants’ attention is directed to the broadness of the claims that recite no specific ingredients resulting in the claimed viscosity” and repeats her arguments combining the ‘642 Patent and the

‘145 Patent. Examiner Answer, p. 29. Applicant’s arguments previously made with respect to the ‘145 Patent and the ‘642 Patent herein and in Applicant’s opening brief are hereby incorporated by reference. Even if the ‘145 Patent and the ‘642 Patent were properly combined, they do not render the claimed invention obvious because they fail to teach or suggest the viscosity, much less the specific ranges called for by claims 8-12 (Group 4). Further, even if a *prima facie* case of obviousness was established, long felt need and unexpected result (*See* p. 17-18, *supra*) have been proven overcoming the rejection, which should be removed.

Issue 9

Whether claims 4, 5, 8-12, 34, and 35 are unpatentable under 35 U.S.C. §103(a) over the ‘642 Patent in view of the ‘145 Patent.

The Examiner has not fully responded to Applicant’s arguments and the Examiner has not met her burden of establishing a *prima facie* case of obviousness. The Examiner repeats the arguments she made under Issue 8 and in particular, Issue 8, Section b, Group 3 and Section c, Group 4 in the Examiner’s Answer. Examiner Answer, p. 29.

As discussed above at pages 10-12, 16-19, and 24-27, the ‘642 Patent and the ‘145 Patent fail to teach the claimed active ingredient particle sizes and the claimed viscosity. It is inconsequential whether the ‘642 Patent teaches droplet sizes of an emulsion being between 50-1000 microns because the claims do not (and never did) have any limitations pertaining to the droplet size of the emulsion. Rather, the pending claims pertain to the particle size of the insoluble dermatologically active ingredient (*see* claim 4). Further, the ‘145 Patent teaches away from the viscosity and particle sizes of the claimed invention because a viscosity of 150 cps and a globule size range of 0.50 to 1 micron (which is not the particle size and is irrelevant to particle

size) are significantly below the viscosities and particle sizes called for by the pending claims. *See* p. 24-28, *supra*.

Again, the Examiner incorrectly asserts her “result-effective variable argument” about particle size. *See* p. 18-19, *supra*.

Therefore, even if the ‘642 Patent and the ‘145 Patent were properly combined, they fail to establish a *prima facie* case of obviousness because they fail to disclose or suggest each and every element of the claims and assuming it was, long felt need and unexpected result (*See* p. 17-18, *supra*) have been proven overcoming this rejection, which should be removed.

a. Group 3 – Claims 4, 5, 34, and 35

In addition to the arguments set forth above, the ‘642 Patent and the ‘145 Patent also do not teach the specific active ingredient particle sizes as described in claims 4, 5, 34, and 35 (Group 3). As discussed above at pages 24-27, the ‘145 Patent does not teach or suggest the active ingredient particle sizes. Thus, the ‘145 Patent fails to teach or suggest the claimed invention.

Further, even if the ‘642 Patent and the ‘145 Patent were properly combined, they do not render the claimed invention obvious because they do not teach or suggest each and every claim element and the rejection should be removed. Even if a *prima facie* case of obviousness was established, long felt need and unexpected result (*See* p. 17-18, *supra*) have been proven overcoming the rejection, which should be removed.

b. Group 4 – Claims 8, 9, 10, 11, and 12

In addition to the arguments set forth above, the '642 Patent and the '145 Patent also do not teach the specific viscosities using specific viscometers as described in claims 8-12 (Group 4). Therefore, even if the '145 Patent and the '642 Patent were properly combined, they fail to render the claims obvious because they do not teach or suggest the viscosity, much less the specific ranges called for by claims 8-12. Further, even if a *prima facie* case of obviousness was established, long felt need and unexpected result (*See* p. 17-18, *supra*) have been proven overcoming the rejection, which should be removed.

Issue 10

Whether claims 8-12 are unpatentable under 35 U.S.C. §103(a) over the '766 Patent in view of the '145 Patent.

The Examiner has not fully responded to Applicant's arguments and the Examiner has not met her burden of establishing a *prima facie* case of obviousness.

As discussed above at pages 19-22 and 24-27 and in Applicant's opening brief, the '766 Patent and the '145 Patent fail to teach or suggest the claimed viscosity and the specific viscosities of claims 8-12. The '145 Patent actually teaches away from the present invention because of the extremely low viscosity of 150 cps.

Therefore, even if the '766 Patent and the '145 Patent were properly combined, they fail to establish a *prima facie* case of obviousness because their combination does not disclose or suggest each and every claim element of claims 8-12 (Group 4). Moreover, even if their combination did result in all of the elements of the claims, the non-obviousness is amply

demonstrated by the long-felt need and unexpected result (*See* p. 17-18, *supra*) for this invention. This rejection should be removed.

Issue 11

Whether claims 1-18, 34, and 35 are unpatentable under 35 U.S.C. §103(a) over the ‘855 Patent in view of the ‘642 Patent.

The Examiner has not fully responded to Applicant’s arguments and the Examiner has not met her burden of establishing a *prima facie* case of obviousness. The Examiner has repeated her arguments with respect to the ‘642 Patent relating to particle sizes and viscosities. Examiner Answer, p. 30. Applicant hereby incorporates by reference the arguments set forth above with respect to the ‘642 Patent.

The Examiner asserts that “[w]etting of the pad of the prior art before use does not constitute a teaching away from the present claims and the product of the prior art makes the present claims obvious because wetting of the pad before use is directed to intended use of the pad, and the present claims do not exclude wetting of the pad before use.”

As previously discussed in Applicant’s opening brief, the ‘855 Patent pertains to a “substantially dry, disposable, personal cleansing article useful for both cleansing the skin or hair and delivering skin care actives to the skin or hair.” *See* Opening Brief, p. 52-56. The cleansing article works by application of water to the article by the user and working up a lather prior to application. *Id.* This flies in the face of the present invention and the ‘855 Patent teaches away from the presently claimed invention. The Examiner’s argument is completely wrong and her evaluation of the teaching of the ‘855 Patent stretches the disclosure beyond common sense.

The '642 Patent does not make up for the deficiencies of the '855 Patent. The '642 Patent does not teach or suggest the claimed viscosity or the particle sizes of the insoluble dermatologically active ingredient and they do not necessarily flow from the disclosure of the prior art. *See* p. 10-12 and 16-19, *supra*. Further, there is no motivation to combine these references because the '855 Patent teaches a substantially dry pad and the '642 teaches a pad with the liquid composition already on the pad ready for application once removed from the package.

Therefore, even if the '855 Patent and the '642 Patent were properly combined, they do not render the claims obvious because they fail to teach or suggest each and every claim element and there is no motivation to combine the references. Further, even if a *prima facie* case of obviousness was established, long felt need and unexpected result (*See* p. 17-18, *supra*) have been proven overcoming the rejection, which should be removed.

a. Group 2 – Claim 2

In addition to the arguments set forth above, the '855 Patent and the '642 Patent also do not teach the limitations of claim 2 (Group 2). This is an example of when the Examiner incorrectly labeled a claim limitation as an intended use. *See* p. 12, *supra*.

Therefore, even if the '855 Patent and the '642 Patent were properly combined, they fail to render the claims obvious because they do not teach or suggest all of the limitations of the claim. Moreover, even if their combination did result in all of the elements of the claims, the non-obviousness of the combination is amply demonstrated by the long-felt need and unexpected result (*See* p. 17-18, *supra*) for this invention. The rejection should be removed.

b. Group 3 – Claims 4, 5, 34, and 35

In addition to the arguments set forth above, the ‘855 Patent and the ‘642 Patent also fail to disclose or suggest the specific active ingredient particle sizes as disclosed in claims 4, 5, 34, and 35 (Group 3). Again, the Examiner asserts her “result-effective variable argument” regarding particle size. *See* p. 18-19, *supra*.

Therefore, even if the ‘855 Patent and the ‘642 Patent were properly combined, they fail to render the claims obvious because they fail to teach or suggest the particle sizes of the active ingredient. Moreover, even if their combination did result in all of the elements of the claims, the non-obviousness of the combination is amply demonstrated by the long-felt need and unexpected result (*See* p. 17-18, *supra*) for this invention. This rejection should be removed.

c. Group 4 – Claims 8, 9, 10, 11, and 12

In addition to the arguments set forth above, the ‘855 Patent and the ‘642 Patent also fail to teach or suggest the specific viscosities as described in claims 8-12 (Group 4). The Examiner merely dismisses these claims by stating that “appellants’ attention is directed to the broadness of the claims that recite no specific ingredients resulting in the claimed viscosity” and just cites her assertions made under her anticipation and obviousness rejection. Examiner Answer, p. 33. In light of the fact that the prior art fails to teach or suggest the viscosities set forth in the claims, the prior art cannot and does not render the claims obvious.

Therefore, even if the ‘855 Patent and the ‘642 Patent were properly combined they fail to render the claims obvious because they fail to disclose or suggest the viscosity, much less the specific ranges called for by claims 8-12. Moreover, even if their combination did result in all of

the elements of the claims, the non-obviousness of the combination is amply demonstrated by the long-felt need and unexpected result (*See* p. 17-18, *supra*) for this invention. The rejection should be removed.

Issue 12

Whether claims 4, 5, 8-12, 34, and 35 are unpatentable under 35 U.S.C. §103(a) over the ‘855 Patent in view of the ‘642 Patent and further in view of the ‘145 Patent.

The Examiner has not fully responded to Applicant’s arguments and the Examiner has not met her burden of establishing a *prima facie* case of obviousness. The Examiner asserts the same arguments made in her answer with respect to Issue 11. Examiner Answer, p. 34.

Applicant herein incorporates by reference the arguments previously made with respect to the ‘855 Patent, the ‘642 Patent, and the ‘145 Patent, and in particular, those made under Issue 8 and 11.

The Examiner also asserts that there is motivation to combine the references because “one having ordinary skill in the art at the time of the invention would have provided [sic] pad impregnated with emulsion and BPO in a container as disclosed by the combined teachings of the references, and adjust the viscosity and particle sizes of the active agents according to the intended use of the article.” Examiner Answer, p. 34. However, the Examiner has provided no support for this assertion. Further, the ‘855 Patent teaches a substantially dry pad, which teaches away from the present invention and is contrary to the teachings in the ‘642 Patent and the ‘145 Patent. Thus, there is no motivation to combine the references.

Therefore, even if the '855 Patent, the '642 Patent, and the '145 Patent were properly combined, they fail to render the claims obvious because they do not teach all of the limitations of the claim. Further, even if a *prima facie* case of obviousness was established, long felt need and unexpected result (*See* p. 17-18, *supra*) have been proven overcoming the rejection, which should be removed.

a. Group 3 – Claims 4, 5, 34, and 35

In addition to the arguments set forth above, the '145 Patent also fails to teach the specific particle size of the insoluble dermatologically active ingredient of claims 4, 5, 34, and 35 (Group 3). The Examiner fails to address Group 3 as required. Applicant asserts that the '145 Patent does not disclose the particle size for insoluble dermatologically active ingredients, including BPO. As discussed above, the only teaching in the '145 Patent is that of globule size, which is not the particle size. Further, the globule size taught is substantially below (0.5 – 1 micron) and irrelevant to the particle sizes of the claimed invention. Therefore, even if the '855 Patent, the '642 Patent, and the '145 Patent were properly combined they do not render the claims obvious because they do not teach or suggest each and every claim element. Further, even if a *prima facie* case of obviousness was established, long felt need and unexpected result (*See* p. 17-18, *supra*) have been proven overcoming the rejection, which should be removed.

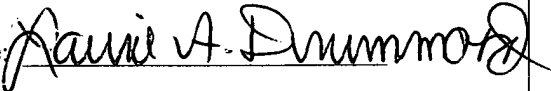
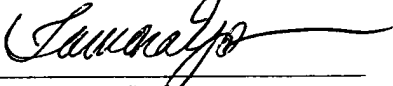
b. Group 4 – Claims 8, 9, 10, 11, and 12

In addition to the arguments set forth above, the '855 Patent, the '145 Patent, and the '642 Patent also do not teach the specific viscosities using specific viscometers as described in claims 8-12 (Group 4). Again, the Examiner fails to address Group 4 as required. Even if the '855 Patent, the '145 Patent, and the '642 Patent were properly combined they fail to render the

claims obvious because they fail to teach or suggest the viscosity, much less the specific ranges called for by claims 8-12. Further, even if a *prima facie* case of obviousness was established, long felt need and unexpected result (*See* p. 17-18, *supra*) have been proven overcoming the rejection, which should be removed.

CONCLUSION

In view of the forgoing discussion, it is respectfully submitted that the Examiner's rejections of claims 1-18, 34 and 35 (Groups 1 to 4) are improper and should be reversed by the Board.

<p>Express Mail Label No. EV 699485710 US</p> <p>Date of Deposit: December 17, 2007</p> <p>I hereby certify that this paper, and the papers and/or fees referred to herein as transmitted, submitted or enclosed, are being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" on the dated indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</p> <p>Name: Laurie A. Drummond</p> <p>Signature: </p>	<p>Respectfully submitted, REED SMITH LLP</p> <p></p> <p>Tamara J. Yorita Registration No.: 53,813 Maryellen Feehery Hank Registration No.: 44,677 William J. McNichol, Jr. Registration No.: 31,179 2500 One Liberty Place 1650 Market Street Philadelphia, PA 19103-7301 (215) 241-5663 Attorneys for Applicant</p>
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IX. Claims Appendix

1. (Previously Amended) A drug delivery system comprising

a pad;

a container; and

a liquid composition, wherein the composition comprises: (1) an effective amount of one or more insoluble dermatologically active ingredients, and (2) an emulsion vehicle for the dermatologically active ingredients,

wherein the composition has a viscosity which is low enough for the composition to substantially uniformly absorb onto the pad via capillary action, and high enough to be substantially retained on the pad, not the container.

2. (Original) The system of claim 1 wherein the viscosity is effective to substantially uniformly deliver the composition to skin when the pad is wiped on the skin.

3. (Original) The system of claim 1 wherein the active ingredient comprises benzoyl peroxide.

4. (Original) The system of claim 3 wherein the benzoyl peroxide comprises particles of less than about 50 microns.

5. (Original) The system of claim 1 wherein the active ingredient comprises particles of about 10 to about 150 microns.

6. (Original) The system of claim 2 wherein the composition is an oil-in-water emulsion.

7. (Original) The system of claim 2 wherein the composition is a water-in-oil emulsion.

8. (Original) The system of claim 2 wherein the composition has a viscosity of about 500 to about 9000 cps measured on a Brookfield viscometer LVT model at about 27°C for 60 seconds and a spindle set for 30 rpm.
9. (Original) The system of claim 2 wherein the composition has a viscosity of about 2000 cps to about 3000 cps measured on a Brookfield viscometer LVT model at about 27°C for 60 seconds and a spindle set for 30 rpm.
10. (Original) The system of claim 2 wherein the composition has a viscosity of about 500 to about 10,000 cps measured on a Brookfield viscometer RVT model with spindle #4 at 20 rpm for 60 seconds at 25°C±1°C.
11. (Original) The system of claim 2 wherein the composition has a viscosity of about 1900 to about 7,000 cps measured on a Brookfield viscometer RVT model with spindle #4 at 20 rpm for 60 seconds at 25°C±1°C.
12. (Original) The system of claim 2 wherein the composition has a viscosity of about 4500 to about 6,500 cps measured on a Brookfield viscometer RVT model with spindle #4 at 20 rpm for 60 seconds at 25°C±1°C.
13. (Original) The system of claim 1 wherein the pad comprises one or more woven materials.
14. (Original) The system of claim 1 wherein the pad comprises one or more non-woven materials.
15. (Original) The system of claim 1 wherein the container comprises a material comprised of metal substantially coated with one or more plastics on at least one surface, and one sheet of the material is heat sealed to a second sheet of the material, and the heat sealed materials contain the pad and the composition without leaking.

16. (Original) The system of claim 1 wherein the active ingredient comprises one or more antifungals.

17. (Original) The system of claim 1 wherein the active ingredient comprises one or more of the group consisting of prodrugs, cosmeceuticals, herbal medicines, traditional medicines, and cutaneously active cosmetic ingredients.

18. (Original) The system of claim 1 further comprising one or more soluble dermatologically active ingredients.

19. (Withdrawn) A drug delivery system comprising

a non-woven pad;

a liquid composition, wherein the composition comprises benzoyl peroxide, starch, carbomer, disodium EDTA, water, glycerin, sodium hydroxide, zinc lactate, glycolic acid, C12-C15 alkyl benzoate, cetearyl alcohol, dimethicone, glyceryl stearate and PEG 100 stearate, steareth 2, steareth 20, and polysorbate 20;

a sealed container, wherein the container comprises a material comprised of metal substantially coated with one or more plastics on at least one surface, and one sheet of the material is heat sealed to a second sheet of the material, and the heat sealed materials contain the pad and the composition without leaking; and

wherein the composition has a viscosity which is low enough for the composition to substantially uniformly absorb onto the pad via capillary action, and high enough to be substantially retained on the pad, not the container.

20. (Canceled)

21. (Withdrawn) The system of claim 19 wherein the viscosity is effective to substantially uniformly deliver the composition to skin when the pad is wiped on the skin.
22. (Withdrawn) The system of claim 19 wherein the benzoyl peroxide comprises particles of less than about 50 microns.
23. (Withdrawn) The system of claim 19 wherein the active ingredient comprises particles of about 10 to about 150 microns.
24. (Withdrawn) The system of claim 19 wherein the composition is an oil-in-water emulsion.
25. (Withdrawn) The system of claim 19 wherein the composition is a water-in-oil emulsion.
26. (Withdrawn) The system of claim 19 wherein the composition has a viscosity of about 500 to about 9000 cps measured on a Brookfield viscometer LVT model at about 27°C for 60 seconds and a spindle set for 30 rpm.
27. (Withdrawn) The system of claim 19 wherein the composition has a viscosity of about 2000 cps to about 3000 cps measured on a Brookfield viscometer LVT model at about 27°C for 60 seconds and a spindle set for 30 rpm.
28. (Withdrawn) The system of claim 19 wherein the composition has a viscosity of about 500 to about 10,000 cps measured on a Brookfield viscometer RVT model with spindle #4 at 20 rpm for 60 seconds at 25°C±1°C.
29. (Withdrawn) The system of claim 19 wherein the composition has a viscosity of about 1900 to about 7,000 cps measured on a Brookfield viscometer RVT model with spindle #4 at 20 rpm for 60 seconds at 25°C±1°C.

30. (Withdrawn) The system of claim 19 wherein the composition has a viscosity of about 4500 to about 6,500 cps measured on a Brookfield viscometer RVT model with spindle #4 at 20 rpm for 60 seconds at 25°C+-1°C.

31. (Withdrawn) The system of claim 19 wherein the pad comprises one or more woven materials.

32. (Withdrawn) The system of claim 19 wherein the pad comprises one or more non-woven materials.

33. (Withdrawn) The system of claim 19 wherein the container comprises a material comprised of metal substantially coated with one or more plastics on at least one surface, and one sheet of the material is heat sealed to a second sheet of the material, and the heat sealed materials contain the pad and the composition without leaking.

34. (Previously Presented) The system of claim 1 wherein the active ingredient comprises particles of up to about 300 microns.

35. (Previously Presented) The system of claim 1 wherein the active ingredient comprises particles of less than about 50 microns.

X. Related Proceedings Appendix

None.